## REMARKS

Claims 1-4, 6-9, 11-14, 16-19, and 21-41 are pending in the present application. Claims 5, 10, and 20, have been cancelled without prejudice or disclaimer to the subject matter set forth therein.

### I. Rejection of Claims 31-34 under 35 U.S.C. §112, second paragraph

Claims 31-34 have been rejected under 35 U.S.C. §112, second paragraph. This rejection under 35 U.S.C. §112, second paragraph, is respectfully traversed.

Independent claim 31 has been amended to enhance the particularity and distinctness of the language used to claim the subject matter that the Applicants regard as their invention. More specifically, claim 31 has been amended to remove the language associated with a second shield so as to remove the antecedent problem.

Accordingly, in view of the amendments and remarks set forth above, the Examiner is respectfully requested to reconsider and withdraw the rejections under 35 U.S.C. §112, second paragraph.

### II. Rejection of Claims 1, 3-6, 8-11, 13-16, 18-21, 23-26, 28-31, 33-35, 37, 38, 40, and 41 under 35 U.S.C. §102(e) over Connelly

Claims 1, 3-6, 8-11, 13-16, 18-21, 23-26, 28-31, 33-35, 37, 38, 40, and 41 have been rejected under 35 U.S.C. §102(e) as being anticipated by Connelly (US 2002/0038135). This rejection of claims , 3-6, 8-11, 13-16, 18-21, 23-26, 28-31, 33-35, 37, 38, 40, and 41 under 35 U.S.C. §102(e) over Connelly is respectfully traversed.

As respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the Applicant conceived or invented the subject matter, which was disclosed but not claimed in published US Patent Application Number US 2002/0038135 filed by the Applicant and others, as claimed in originally presented claims of the above-identified application.

Moreover, as respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the Applicant is the sole inventor of the subject matter, which was disclosed but not claimed in published US Patent Application Number US 2002/0038135 filed by the Applicant and others, as claimed in originally presented claims of the above-identified application.

Lastly, as respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the subject matter, corresponding to the originally presented claims of the above-identified application and disclosed in Published US Patent Application Number US 2002/0038135, was derived from the Applicant.

Therefore, in view of the statements made in the attached Affidavit under 37 C.F.R. 1.132, Connelly is not a valid prior art reference under 35 U.S.C. §102(e) because the claimed invention corresponding to the originally presented claims of the above-identified application and disclosed by Connelly is not by another.

Accordingly, in view of the attached Affidavit under 37 C.F.R. 1.132 and remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §102(e) over Connelly.

## III. Rejection of Claims 2, 7, 12, 17, 22, 27, 32, 36, and 39 under 35 U.S.C. §103 over Connelly in view of Mulier

Claims 2, 7, 12, 17, 22, 27, 32, 36, and 39 have been rejected under 35 U.S.C. §103 as being unpatentable over Connelly (US 2002/0038135) in view of Mulier (US-A-3,718,142). This rejection of claims 2, 7, 12, 17, 22, 27, 32, 36, and 39 under 35 U.S.C. §103 over Connelly in view of Mulier is respectfully traversed.

As respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the Applicant conceived or invented the subject matter, which was disclosed but not claimed in published US Patent Application Number US 2002/0038135 filed by the Applicant and others, as claimed in originally presented claims of the above-identified application.

Moreover, as respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the Applicant is the sole inventor of the subject matter, which was disclosed but not claimed in published US Patent Application Number US 2002/0038135 filed by the Applicant and others, as claimed in originally presented claims of the above-identified application.

Lastly, as respectfully submitted in the attached Affidavit under 37 C.F.R. 1.132, the subject matter, corresponding to the originally presented claims of the above-identified application and disclosed in Published US Patent Application Number US 2002/0038135, was derived from the Applicant.

Therefore, in view of the statements made in the attached Affidavit under 37 C.F.R. 1.132, Connelly is not a valid prior art reference under 35 U.S.C. §102(e) because the claimed invention corresponding to the originally presented claims of the above-identified application and disclosed by Connelly is not by another.

Accordingly, in view of the attached Affidavit under 37 C.F.R. 1.132 and remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §103 over Connelly.

**IV. Rejection of Claims 1, 2, 5, 6, 7, and 10 under 35 U.S.C. §103 over Mulier**

Claims 1, 2, 5, 6, 7, and 10 have been rejected under 35 U.S.C. §103 as being unpatentable over Mulier (US-A-3,718,142). This rejection of claims 1, 2, 5, 6, 7, and 10 under 35 U.S.C. §103 over the teachings of Mulier is respectfully traversed.

As respectfully submitted above, amended independent claim 1 sets forth a cardiac assist system, comprising a primary device housing, the primary device housing having a control circuit therein; a shielding formed around the primary device housing to shield the primary device housing and any circuits therein from electromagnetic interference; and a biocompatible material formed around the shielding. The biocompatible material is a non-permeable diffusion resistant biocompatible material.

Moreover, as respectfully submitted above, amended independent claim 6 sets forth a tissue invasive device, comprising a primary device housing, the primary device housing having a control circuit therein; a shielding formed around the primary device housing to shield the primary device housing and any circuits therein from electromagnetic interference; and a biocompatible material formed around the shielding. The biocompatible material is a non-permeable diffusion resistant biocompatible material

In formulating the present rejection under 35 U.S.C. §103, the Examiner alleges that Mulier teaches an implantable pacemaker which has a metallic shielding to protect internal circuitry from EMI. The Examiner further alleges that it would be considered obvious to have the external layer of the housing of Mulier be biocompatible since such housing is implanted inside the patient. Implanted devices must be biocompatible otherwise adverse tissue reaction would occur. From these allegations, the Examiner concludes that the presently claimed invention would have been obvious to one of ordinary skill in the art in view of Mulier in order

to further prevent externally produced EMI from interfering with the operation of the pacemaker. These positions by the Examiner are respectfully traversed in view of the claims presented above.

Mulier teaches a thin film layer of metal deposited over the epoxy surface of the cardiac stimulator (Column 1, lines 58-59). Mulier further teaches that the metal layer must be impervious to the action of living body fluids (Column 1, lines 60-62). Lastly, Mulier teaches that the epoxy case must be permeable to hydrogen gas as well as the metal layer (Column 1, lines 27-45).

In contrast, the presently claimed invention clearly sets forth that the shield is covered by a biocompatible material that is non-permeable and diffusion resistant. Mulier actually teaches away from a biocompatible layer being formed upon the shield because Mulier explicitly teaches that the metal layer must be a composition to be in contact with living body fluids and so thin so that pinholes can be created to allow hydrogen gas to escape from the pacemaker canister. If the device of Mulier included another layer over the metal shield that layer would hinder the formation of pinholes in the metal layer.

Moreover, Mulier clearly teaches that a critical characteristic of the layers around the stimulator is that these layers are permeable such that hydrogen gas can escape the stimulator. Therefore, any further layers formed upon the metal layer of Mulier must be permeable to hydrogen gas; in contrast, the presently claimed invention includes a biocompatible layer that is non-permeable and diffusion resistant.

In summary, Mulier fails to suggest a further layer of biocompatible material over the shield because the shield is already made of a composition that is able to be in contact with living body fluids. Furthermore, Mulier teaches, contrary to the claimed invention, that all the layers surrounding the stimulator must be permeable to hydrogen gas. Therefore, Mulier fails to teach or suggest the presently claimed invention, as set forth by amended independent claims 1 and 6.

With respect to dependent claims 2 and 7, the Applicant, for the sake of brevity, will not address the reasons supporting patentability for these individual dependent claims, as these claims depend directly from allowable independent claims 1 and 6, respectively, for the reasons set forth above. The Applicant reserves the right to address the patentability of theses dependent claims at a later time, should it be necessary.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §103 over Mulier.

**V. Rejection of Claims 3, 4, 8, and 9 under 35 U.S.C. §103 over Mulier in view of Luo et al.**

Claims 3, 4, 8, and 9 have been rejected under 35 U.S.C. §103 as being unpatentable over Mulier (US-A-3,718,142) in view of Luo et al. This rejection of claims 3, 4, 8, and 9 under 35 U.S.C. §103 over the teachings of Mulier in view of Luo et al. is respectfully traversed.

With respect to dependent claims 3, 4, 8, and 9, the Applicant, for the sake of brevity, will not address the reasons supporting patentability for these individual dependent claims, as these claims depend directly or indirectly from allowable independent claims 1 and 6, respectively, for the reasons set forth above. The Applicant reserves the right to address the patentability of theses dependent claims at a later time, should it be necessary.

Accordingly, in view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §103 over Mulier in view of Luo et al.

**VI. Rejection of Claims 11, 12, 15, 16, 17, and 20 under 35 U.S.C. §103 over Mulier in view of Nappholz et al.**

Claims 11, 12, 15, 16, 17, and 20 have been rejected under 35 U.S.C. §103 as being unpatentable over Mulier (US-A-3,718,142) in view of Nappholz et al. (US-A-5,766,227). This rejection of claims 12 and 13 under 35 U.S.C. §103 over the teachings of Mulier in view of Nappholz et al. is respectfully traversed.

As respectfully submitted above, amended independent claim 11 sets forth a cardiac assist system, comprising a primary device housing, the primary device housing having a control circuit therein; a shielding formed around the primary device housing to shield the primary device housing and any circuits therein from electromagnetic interference; a biocompatible material formed around the shielding; and a detection circuit, located in the primary device housing, to detect an electromagnetic interference insult upon the cardiac assist system. The control circuit places the cardiac assist system in an asynchronous mode upon detection of the electromagnetic interference insult by the detection system. The biocompatible material is a non-permeable diffusion resistant biocompatible material.

Moreover, as respectfully submitted above, amended independent claim 16 sets forth a tissue invasive device, comprising a primary device housing, the primary device housing having a control circuit therein operating in a first mode; a shielding formed around the primary device housing to shield the primary device housing and any circuits therein from electromagnetic interference; a biocompatible material formed around the shielding; and a detection circuit, located in the primary device housing, to detect an electromagnetic interference insult upon the tissue invasive device. The control circuit places the tissue invasive device in a second mode upon detection of the electromagnetic interference insult by the detection system. The biocompatible material is a non-permeable diffusion resistant biocompatible material

In formulating the present rejection under 35 U.S.C. §103, the Examiner alleges that Mulier teaches all of the subject matter of the above claims except the detection circuit to detect a phase timing of an external electromagnetic field. The Examiner further alleges that it would be considered obvious to have the external layer of the housing of Mulier be biocompatible since such housing is implanted inside the patient. Implanted devices must be biocompatible otherwise adverse tissue reaction would occur.

To meet the deficiency in the teachings of Mulier, the Examiner proposes to modify Mulier with the teachings of Nappholz et al. The Examiner alleges that Nappholz et al. teaches EMI detection in a pacemaker. From these allegations, the Examiner concludes that it would have been obvious to one of ordinary skill in the art to have such a detection circuit in the device of Mulier in order to further prevent externally produced EMI from interfering with the operation of the pacemaker. These positions by the Examiner are respectfully traversed in view of the claims presented above.

As noted above, Mulier teaches a thin film layer of metal deposited over the epoxy surface of the cardiac stimulator (Column 1, lines 58-59). Mulier further teaches that the metal layer must be impervious to the action of living body fluids (Column 1, lines 60-62). Lastly, Mulier teaches that the epoxy case must be permeable to hydrogen gas as well as the metal layer (Column 1, lines 27-45).

In contrast, the presently claimed invention clearly sets forth that the shield is covered by a biocompatible material that is non-permeable and diffusion resistant. Mulier actually teaches away from a biocompatible layer being formed upon the shield because Mulier explicitly teaches that the metal layer must be a composition to be in contact with living body fluids and so thin so

that pinholes can be created to allow hydrogen gas to escape from the pacemaker canister. If the device of Mulier included another layer over the metal shield that layer would hinder the formation of pinholes in the metal layer.

Moreover, Mulier clearly teaches that a critical characteristic of the layers around the stimulator is that these layers are permeable such that hydrogen gas can escape the stimulator. Therefore, any further layers formed upon the metal layer of Mulier must be permeable to hydrogen gas; in contrast, the presently claimed invention includes a biocompatible layer that is non-permeable and diffusion resistant.

In summary, Mulier fails to suggest a further layer of biocompatible material over the shield because the shield is already made of a composition that is able to be in contact with living body fluids. Furthermore, Mulier teaches, contrary to the claimed invention, that all the layers surrounding the stimulator must be permeable to hydrogen gas. Therefore, Mulier fails to teach or suggest the presently claimed invention, as set forth by amended independent claims 11 and 16.

Moreover, Nappholz et al. fails to teach or suggest a further layer of biocompatible material over the shield and/or that any biocompatible material is non-permeable and diffusion resistant.

Therefore, Mulier and Nappholz et al., singly or in combination fail to teach or suggest a further layer of biocompatible material over the shield and/or that any biocompatible material is non-permeable and diffusion resistant, as set forth by amended independent claims 11 and 16.

With respect to dependent claims 12 and 17, the Applicant, for the sake of brevity, will not address the reasons supporting patentability for these individual dependent claims, as these claims depend directly or indirectly from allowable independent claims 1 and 6, respectively, for the reasons set forth above. The Applicant reserves the right to address the patentability of theses dependent claims at a later time, should it be necessary.

Accordingly, in view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §103 over Mulier in view of Nappholz et al.

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## VII. Rejection of Claims 13, 14, 18, and 19 under 35 U.S.C. §103 over Mulier in view of Nappholz et al. and Luo et al.

Claims 13, 14, 18, and 19 have been rejected under 35 U.S.C. §103 as being unpatentable over Mulier (US-A-3,718,142) in view of Nappholz et al. (US-A-5,766,227) and Luo et al. This rejection of claims 12 and 13 under 35 U.S.C. §103 over the teachings of Mulier in view of Nappholz et al. and Luo et al. is respectfully traversed.

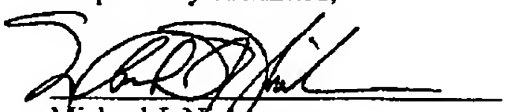
With respect to dependent claims 13, 14, 18, and 19, the Applicant, for the sake of brevity, will not address the reasons supporting patentability for these individual dependent claims, as these claims depend directly or indirectly from allowable independent claims 11 and 16, respectively, for the reasons set forth above. The Applicant reserves the right to address the patentability of theses dependent claims at a later time, should it be necessary.

Accordingly, in view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw this rejection under 35 U.S.C. §103 over Mulier in view of Nappholz et al. and Luo et al.

## CONCLUSION

Accordingly, in view of all the amendments and reasons set forth above, the Examiner is respectfully requested to reconsider and withdraw all the present rejections. Also, an early indication of allowability is earnestly solicited.

Respectfully submitted,



Michael J. Nickerson
Registration No. 33,265
Basch & Nickerson LLP
1777 Penfield Road
Penfield, New York 14526
Telephone: (585) 899-3970

MJN/mjn